Cost-effective improvement in endometrial cancer diagnosis by the incorporation of molecular analysis. Pilot and randomized study.

S.Fernandez-Gonzalez, M. Amoros, S.M. Arroyuelo, D. Barazi, M. Cararach, J. Fernandez, LL. Fernandez de Castillo, L. Jofre, L.Pallares, M. Palau, M.J. Rodriguez-Domingo, L. Santos, M.E. Fernandez-Montoli, X. Sanz, G. Tena, J. Ponce

Department of Gynecology Oncology
Hospital Universitari de Bellvitge, L'Hospitalet de Llobregat, Barcelona, Spain
Fundació Institut d'Investigació Biomèdica de Bellvitge (IDIBELL)

INTRODUCTION

The histopathology remains the gold standard to diagnose endometrial cancer (EC) from endometrial biopsy (EB). Molecular tests have recently emerged as a useful tool to classify EC according to its prognosis [1][2][3]. However, there is currently no published protocol that includes molecular diagnosis of postmenopausal women with abnormal uterine bleeding (AUB).

The main objetive was to compare the estimated costs and explorations regarding a classical algorithm of AUB diagnose vs a molecular test algorithm (Gynec®-Dx). The secondary objective was to test the sensitivity (S), specificity (E), positive and negative predictive values (PPV and NPV of the molecular test.

METHODS

We present a prospective study performed in postmenopausal women who presented AUB between 2009-2014. Seven centers recruited the patients. Three of them follow the classical diagnosis algorithm (group 1) and four centers follow the one that incorporates a molecular test (Gynec-Dx) performed on the remnants of aspirates (group 2). In group 2, when both the endometrial biopsy and the molecular test were negative, the consequent explorations were considered as **"out of protocol"**.

Clinical data, number of biopsies, ultrasounds, hysteroscopies and visits were compared between groups. In addition, the sensitivity (S), specificity (E), positive and negative predictive values (PPV and NPV) of the molecular test were calculated.

RESULTS

Figure 1 Protocol of classical group

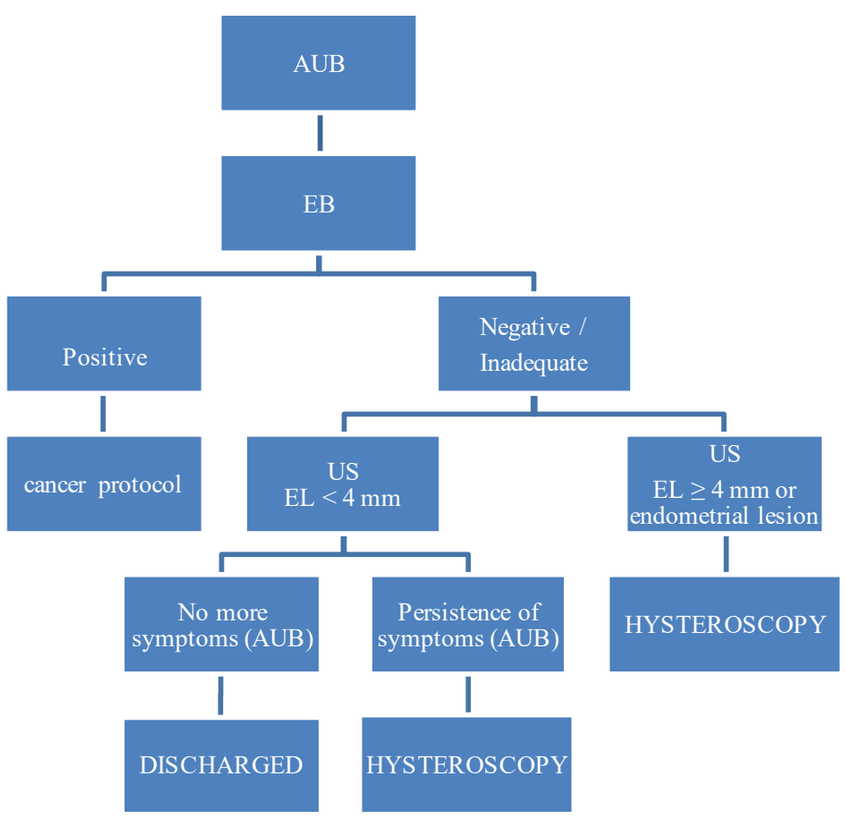

Figure 2 Protocol of molecular group

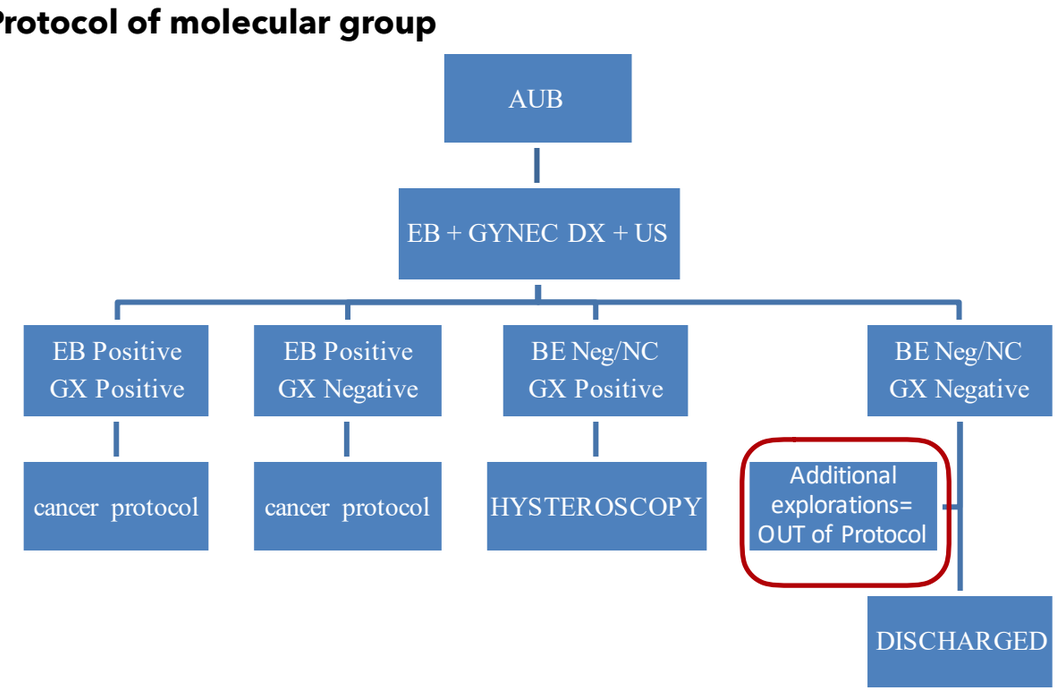

Table 1 Clinical characteristics of the patients

	Classical (n=51)	Molecular (n=43)	*p-value*
Age (years, mean ± SD)	58,51 ± 8,41	59,60 ± 10,72	0.580
Age at menopause (years, mean ± SD)	49,88 ± 3,60	48,30 ± 3,88	0.044
BMI (kg/m^2)	29,35 ± 5,76	29,25 ± 6,30	0.934
Parity (n, mean ± SD)	2,24 ± 1,14	2,33 ± 1,69	0.759
Tamoxifen (%)	1 (2)	0	0.759
Hormonal replacement treatment	0	0	

Table 2 Outcomes

	Classical (n=51)	Molecular (n=43)	*p-value*
Biopsy (n, %)			0.317
No malignancy	33 (66%)	28 (65,1%)	
Polyp	11 (22%)	6 (14%)	
Hyperplasia	0	2 (4,8%)	
Endometrial cancer	1 (2%)	3 (7,14%)	
Negative / Inadequate	5 (10%)	3 (7%)	
US			0.071
Endometrium < 4mm	29 (57%)	16 (38,1%)	
Endometrium ≥ 4mm	22 (43%)	26 (61,9%)	
Results			0.143
Discharged	29 (59%)	29 (71%)	
Hysteroscopy	19 (39%)	9 (22%)	
Protocol of cancer	1 (2%)	3 (7%)	

Table 3 Total number of explorations

	Classical (n=51)	Molecular (n=43)	
	Protocol IN	Protocol IN	Protocol OUT
Gynec®-Dx	-	43	-
Biopsy	51	43	6
US	58	41	22
Histeroscopy	26	2	11
Visits	189	100	53
TOTAL	**324**	**229**	**92**

Table 4 Outcomes of the molecular test

	Endometrial cancer	No cancer	
Gynec®-Dx (+)	3	3	6
Gynec®-Dx (-)	0	37	37
	3	40	43

Sensitivity = 100%

Specificity = 92.5%

Positive Predictive Value = 50%

Negative Predictive Value = 100%

CONCLUSIONS

According to our results, the incorporation of a molecular test for the diagnosis of EC in postmenopausal women who complained with AUB, reduces the number of explorations. Consequently, the molecular algorithm should be considered as more cost-effective than conventional algorithms.

REFERENCES

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